

United States Surgical Corporation
510(k) Premarket Notification
AUTO SUTURE* Modified VCS* Clip** Applier

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SUMMARY OF INFORMATION SUPPORTING **K962043**
SAFETY AND EFFECTIVENESS:

The AUTO SUTURE* Modified VCS* Clip** device is identical in safety and effectiveness to its currently marketed predicate - U.S. Surgical Corp.'s Vascular Anastomosis Clip** applier - 510(k) #K933887. This clip applier has been marketed for the closure of arteriotomies and venotomies, the attachment of synthetic vascular prosthesis, and the creation of everting anastomoses in blood vessels and other small tubular structures. The performance evaluation of this clip applier by USSC's PreQuality Assurance Laboratory and an independently contracted research laboratory have determined that the clip has additional utility for the approximation of soft tissues such. The information included in this notification demonstrates that the device is substantially equivalent to its predicate in respect to design, function, performance, labeling and sterilization.

- Both the subject and predicate devices are designed to apply a single titanium clip to soft tissues.
- Both the subject and predicate device share the same indications. In addition, the subject device is additionally indicated for the approximation of soft tissues outside of the vascular arena.
- Both the subject devices and other currently marketed United States Surgical Corporation devices are manufactured in the same facilities, using similar processes and controls.
- Both the subject devices and other currently marketed United States Surgical Corporation devices are packaged in the same facilities using similar processes and controls.
- Both the subject and predicate devices perform the exact same function in the same way.
- Both the subject and predicate devices are manufactured from the exact same bio-approved materials